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EXAMINER

FOX, DAVID T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|--------------------------------------|-------------------------------------|
| Application No. 09/503,945 | Applicant(s) Hamada et al |
| Examiner Fox | Group Art Unit 1638 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **3-** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 11/13/02**
- ☒ Responsive to communication(s) filed on _____.
 - ☒ This action is **FINAL**.
 - ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 11-29**
- ☒ Claim(s) _____ is/are pending in the application.
 - Of the above claim(s) **24-25** is/are withdrawn from consideration.
 - ☐ Claim(s) _____ is/are allowed.
 - ☒ Claim(s) **11, 13-23 and 26-29** is/are rejected.
 - ☒ Claim(s) **12** is/are objected to.
 - ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☒ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment of 13 November 2002 cancelled claims 1-10 and submitted new claims 11-29. The amendment of 13 November 2002 overcame the outstanding objections to the claims and rejections under 35 USC 112, second paragraph. The certified translation of 13 November 2002 overcame the rejection under 35 USC 102(a).

Claim 12 is objected to for its omission of the article --the-- after "comprising".

Newly submitted claims 24-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 11-23 and 26-29 correspond to previously examined claims 1-10, namely a first product comprising a mutant barnase gene and a first method of its use, which method comprises plant transformation for the recovery of male-sterile plants. Newly submitted claims 24-25 are drawn to a second method of use of already generated mutant barnase genes, namely bacterial transformation, which requires different starting materials, transformation and culture steps, and gene regulatory sequences, each not required by the previously examined invention. Furthermore, the claimed invention involving the mutant barnase gene and methods of its use to confer male sterility does not constitute an advance over the prior art, since it is taught or suggested by prior art as set forth in the last Office action and the instant Office action. Accordingly, the claims are not linked by a single special technical feature under PCT Rule 13.1. Therefore, the claims are not properly examinable together.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 13-14, 17-23 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last Office action on pages 3-4 for claims 1-4 and 7-10.

Claims 13-14, 17-23 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a mutant barnase gene which encodes SEQ ID NO:2 and which contains an insertion of a T nucleotide at position 15 (calculated from the first nucleotide of the translation initiation codon), does not reasonably provide enablement for any mutant barnase gene which contains a multitude of non-exemplified deletions, additions or substitutions yet retains the ability to encode a functional barnase protein, optionally due to frameshift recoding. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last Office action for claims 1-4 and 7-10.

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Claims 11, and 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claims 11, 15 and 16 are indefinite in their recitation of "initiation codon" as it is unclear whether this refers to transcriptional or translational initiation. Insertion of --translation-- before "initiation" would obviate this rejection.

Claims 14 and 18 are indefinite in their recitation of "1- to 27-positions" as it is unclear whether this refers to amino acid residues or whether this refers to nucleotides. Furthermore, the reference point used to calculate the position numbering is unclear.

Claims 13, 17, 21-23 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/26283 (PLANT GENETIC SYSTEMS), as stated on pages 6-7 of the last office action for claims 1-4 and 7-10.

Claims 13, 17 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Serrano et al, as stated on page 7 of the last office action for claims 1-3.

Claims 13, 17 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Jucovic et al, as stated on pages 7-8 of the last office action for claims 1-3.

Claims 13, 17, 21-23 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/26283 (PLANT GENETIC SYSTEMS) taken with Serrano et al, in view of Jucovic et al, as stated on pages 8-9 of the last office action for claims 1-4 and 7-10.

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Claims 11, 12, 14-16 and 18-20 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a barnase gene which comprises an inserted T at nucleotide 15 (calculated from the first nucleotide of the translation initiation codon) which causes a frameshift, or which mutant barnase gene comprises at least nucleotides 1-27 of SEQ ID NO:3, wherein said mutated barnase genes are capable of expressing functional barnase proteins due to frameshift recoding, or plants transformed therewith under the control of an anther-specific promoter.

Claim 12 is objected to for a grammatical error, as stated above.

No claim is allowed.

Applicants' arguments filed 13 November 2002, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicants urge that the written description rejection is improper, given the disclosure of a particular mutation, namely the T insertion at position 15, coupled with a demonstration of its function to cause frameshift recoding, as illustrated in the specification and also as illustrated by the Hamada declaration of 13 November 2002 submitted under 37 CFR 1.132. Applicants also urge that the enablement rejection is improper, given the ability of the artisan of ordinary skill to evaluate different mutant barnase sequences for their ability to cause frameshift mutation, frameshift recoding, and/or male sterility.

The Examiner maintains that claims limited to genes which retain the T insertion at position 15 and which retain the ability to encode a barnase protein of SEQ ID NO:2 were not

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subjected to the rejections under 35 USC 112, first paragraph. However, the rejected claims are broadly drawn to any additional mutation of these initial insertion mutations via the substitution, deletion, insertion or addition of a multitude of nucleotides at any position (claims 13-14, 17-18, 21-23 and 26-29). It is unclear whether such undefined and uncharacterized additional mutations would even result in a barnase-encoding gene.

Furthermore, claims 19-20 are drawn to any barnase gene containing any mutation at any residue which causes a frameshift mutation and which allows frameshift recoding. No guidance in the specification has been provided for any other frameshift mutation, other than the one at position 15, which confers this ability. Applicants also admit on page 8 of the specification, lines 13-20, that frameshift recoding is highly sequence-specific. It is noted that the deletion at position 333 was never evaluated in the absence of the insertion at position 15, and since position 333 is at the very end of the protein-encoding sequence, it is unlikely that the mutation at this position alone would have any effect on frameshift or the expression of a functional barnase protein.

Given the lack of demonstration of function of the broadly claimed sequences, an adequate written description of the broadly claimed genus has not been provided. See the Revised Written Description Guidelines, Federal Register Vol. 66, No. 4, issued 5 January 2001, pages 1099-1111.

Furthermore, given the claim breadth, unpredictability and lack of guidance as set forth in the last office action and above, undue experimentation would have been required by one skilled

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in the art to evaluate the multitude of non-exemplified sequences for their ability to either encode a functional barnase protein capable of conferring male sterility, or to cause frameshift recoding.

Applicants urge that the art rejections are improper, given the cancellation of the previously rejected claims, the presentation of new claims limited to frameshift mutations of the barnase gene which allow frameshift recoding, and the failure of the prior art to teach or suggest the use of such frameshift mutations and frameshift recoding to confer male sterility to plants transformed therewith.

The Examiner maintains that all claims which are clearly limited to mutant barnase genes comprising the exemplified frameshift mutation at position 15 which allows frameshift recoding, wherein said mutant genes encode a functional barnase gene albeit at a lower frequency, were deemed free of the prior art. However, the rejected claims were not so limited. The unspecified addition, deletion, substitution or insertion of an unspecified number of nucleotides at an unspecified number of positions in the initially mutated barnase gene would result in a multitude of sequences which do not necessarily retain the frameshift mutation. For example, the initial insertion of T at position 15, to generate the exemplified "ATGGTACCGGTTATTCA", followed by the deletion of the T at position 14, would result in "ATGGTACCGGTTATCA" wherein the inserted T at position 15 was retained, but wherein the nucleotides at positions 1-27 were now indistinguishable from the sequence of the wild-type gene at those positions. Furthermore, the cited prior art teaches other mutations in sequence, which could have been the result of said

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insertion of a T at position 15, followed by deletion of the T at position 14, followed by said additional mutations.

Furthermore, the claims are broadly drawn to any frameshift mutation at any position which retains the ability to encode a functional barnase protein due to frameshift recoding, or any subsequent mutation following the insertion of a T at position 15. In contrast, Applicants' evidence of unexpected results is limited to sequences which contain an inserted T at position 15 but are otherwise not mutated and which encode a barnase protein of SEQ ID NO:2. See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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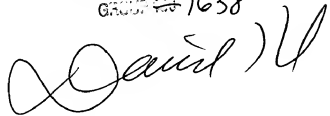
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 17, 2003

DAVID T. FOX
PRINCIPAL EXAMINER
GROUP 1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a stylized flourish at the end.